Institutional Review Board

Renewal/Continuing Protocol Review Application

Face Page

Warning: **Submitting an application that does not meet the requirements set out in the Instruction Packet will delay your project being reviewed and approved.**

1a. TDH IRB#: _____

1b. Protocol Title: _____

2. Starting Date: _____ **3. Ending Date:** _____ **4. Total # of Subjects:** _____

5. Principal Investigator (PI):

Name, Degrees: _____

Address: _____

_____

_____

Phone: _____

E-Mail: _____

6. TDH Contact (If different from PI):

Name, Degrees: _____

Address: _____

_____

_____

Phone: _____

E-Mail: _____

7. Student Investigator, provide your Thesis/Dissertation Chair:

Name: _____

University/Dept: _____

Address: _____

_____

Phone: _____

E-Mail:

For Office Use Only

8. Project Funding Source (Check One):

☐ Internal (TDH)

☐ Innovation Grant (TDH)

☐ Federal Agency _____ Specific Area _____

☐ Thesis/Dissertation: University _____ Department _____

☐ University _____

☐ Private Company _____

9. Principal Investigator's Statement:

In making this application, I certify that I have read and understand the TDH IRB guidelines and procedures which are based on the Belmont Report, and that I fully intend to comply with these policies.

I further acknowledge my responsibility to report any adverse event or significant changes in the protocol.

I agree to obtain written approval for any significant changes prior to their implementation.

I will keep all records pertaining to this research for three (3) years after its completion.

_____ _____

Signature(s): Principal Investigator(s) or Faculty Sponsor(s) **Date Signed**

10. Multi-Site Collaboration:

☐ None ☐ Foreign Site(s) Only†
☐ Domestic Site(s) Only† ☐ Domestic & Foreign Sites†

†See Page 3 of the Instructions Packet.

11. Other IRBs

_____ _____
(Name) (Telephone Number)

_____ _____
(Name) (Telephone Number)

12. Subject Information

a. Characteristics (Check all that apply)

Age Groups	☐ 0-17 years	☐ 18-65 years	☐ 66+ years			
Fetuses	☐ No	☐ Yes				
Pregnant Women	☐ No	☐ Yes				
Elderly/Aged	☐ No	☐ Yes				
Prisoners	☐ No	☐ Yes				
Impaired	☐ No	☐ Yes	☐ Physically	☐ Cognitively	☐ Both	
Compensation/Incentives	☐ No	☐ Yes (Describe)	_____			

b. Exclusions (Check all that apply)

☐ None ☐ All Non-English Speaking
☐ Male ☐ Asian
☐ Female ☐ Black (not of Hispanic origin)
☐ Pregnant Women ☐ Hispanic
☐ Adult ☐ Native American
☐ Child ☐ White (not of Hispanic origin)

c. Will identifying information be collected? ☐ Yes ☐ No

13. Additional Questions

a. Ionizing Radiation Use? (X-rays, radioisotopes, etc.)

☐ None
☐ Medically indicated only (In the Synopsis of Proposal, item #4, please explain)
☐ Research indicated (In the Synopsis of Proposal, item #4, please explain)

b. Investigational New Drug or Device

☐ None ☐ IND ☐ IDE

FDA No. _____
Name: _____
Sponsor: _____
Holder: _____

c. This project involves:

Questionnaires or surveys ?	☐ Yes	☐ No
Medical Chart review?	☐ Yes	☐ No
Biologic Sampling?	☐ Yes	☐ No
Use of biologic samples already collected?	☐ Yes	☐ No
Experimental treatment?	☐ Yes	☐ No
Withholding usual treatment?	☐ Yes	☐ No

d. Submission of Non-English Translations:

This project involves non-English speaking participants.	☐ Yes	☐ No	
Changes were made to the non-English documents.	☐ Yes	☐ No	☐ N/A

Non-English documents that were changed. _____

14. Synopsis of Study Progress (See the Instructions Packet for details)